FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

REGINA HOLCOMB et al,

Plaintiff,

v. CIVIL ACTION NO. 2:12-cv-06302

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

Pending before the court are several *Daubert* motions filed by both the defendant and the plaintiffs. Briefing is complete regarding these motions, and the motions are now ripe for consideration.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 19,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. The parties have retained experts to render opinions regarding the elements of the case's various causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Rule 702 of the Federal Rules of Evidence, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education" and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data;" and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The Supreme Court has established a two-part test to govern the admissibility of expert testimony under Rule 702: the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper. "[E]xpert witnesses have the potential to be both powerful and quite misleading," so the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999); *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431

(4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested;" (2) whether the theory "has been subjected to peer review and publication;" (3) the "known or potential rate of error;" (4) the "existence and maintenance of standards controlling the technique's operation;" and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94). Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("[T]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." (citation omitted)); *Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevance, the second part of the analysis, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (citations and quotation marks omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

III. Preliminary Matters

I begin by addressing a few preliminary matters that affect many of the *Daubert* motions. First, both parties consistently challenge experts' opinions as improper state-of-mind or legal-conclusion testimony. As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding expert opinions on the defendant's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics). The reasonableness of conduct and a party's then-existing state of mind "are the sort of questions that lay jurors have been answering without expert assistance from time immemorial," and therefore, these matters are not appropriate for expert

testimony. *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998); *see also In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.").[1] Likewise, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). An expert may not state his opinion using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

I have diligently applied these rules to previous expert testimony, and I continue to apply them in this case. This does not mean that each objection to state-of-mind or legal-conclusion testimony raised in these motions is valid. But I will not parse the numerous reports and thousand-page depositions for each expert to determine the validity of these same objections. Instead, the onus is on counsel to tailor expert testimony at trial in accordance with the above directive. Therefore, unless otherwise necessary, the remainder of this opinion does not address objections brought against an expert based on improper state-of-mind or legal-conclusion testimony.

[1] On a related note, I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—he or she may not be offered solely as a conduit for corporate information. There is no reason why the plaintiffs require an expert to opine on such facts.

I also note that several of the *Daubert* motions concern expert opinions entirely unrelated to the individual plaintiffs at bar. For example, some experts have opined on general and specific causation with the specific causation portion of the opinion pertaining to wave plaintiffs other than the plaintiffs in this particular case. In addition, the parties filed a total of seventeen *Daubert* motions involving, in many instances, duplicative experts. In an effort to remedy this problem of blanketed, duplicative *Daubert* motions, I directed the parties to file disclosures, indicating who, out of the seventeen challenged experts, they plan to call at trial for each case. *See* Pretrial Order No. 121, at 5–6 [ECF No. 54]. Through these disclosures, I hoped to gain a better understanding of the particular arguments at issue, thereby refining my *Daubert* rulings for the benefit of the receiving judge. Rather than aiding the court in this endeavor, however, the parties effectively ignored the pretrial order, identifying *all* of their challenged experts as probable expert witnesses, or failing to respond at all. *See* Pl.'s Disclosure Required by Pretrial Order No. 121 [ECF No. 55]. Without guidance from the parties to the contrary, I have thus limited my review of the *Daubert* motions to only those arguments and opinions related to the instant plaintiffs. In other words, I disregard arguments included in the briefing directed exclusively at other wave plaintiffs and, consequently, irrelevant to *this* case.

I am also compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*,

57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of an expert's opinion based on its reliability and relevance. In other words, the parties have comparatively examined each expert's opinions and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are remiss, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert opinions and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular opinions and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the

parties' submission of updated expert reports and new objections to the opinions contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of an expert's testimonial opinion may be evaluated at trial. At trial, the opinions will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert opinion testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert opinions offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalization of opinions, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity

is necessary, I believe it is only achievable through live witnesses at trial and I will therefore reserve ruling until expert opinions can be evaluated firsthand.

IV. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude the expert opinions of Drs. Michael Thomas Margolis, Thomas Barker, Jimmy Mays, Peggy Pence, Russell Dunn, Scott Guelcher, Richard Trepeta, Vladimir Iakovlev, Niall Galloway, Bobby L. Shull, and Konstantin Walmsley.

A. Michael Thomas Margolis, M.D.

BSC seeks to exclude the testimony of Michael Thomas Margolis, M.D. Dr. Margolis is a pelvic floor surgeon and urogynecologist who offers general causation opinions in this case.

1. Failure to Consider Studies

First, BSC challenges Dr. Margolis's failure to consider contrary studies. Dr. Margolis has explained his methodology for giving less credence to certain studies than to others. Dr. Margolis states that he has examined other studies that counter his own opinions. To the extent the defendant challenges the reasons Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis's opinions, not their admissibility. The defendant is free to cross-examine Dr. Margolis regarding studies that cut against his opinions. The defendant's motion is **DENIED** on this point.

Second, BSC challenges Dr. Margolis's opinion that there is a greater than 50 percent complication rate of pain in women with polypropylene mesh and slings. In

his deposition, Dr. Margolis acknowledges that contrary studies exist, and I do not doubt that Dr. Margolis reviewed contrary studies. However, his methodology may be flawed if he does not provide an adequate explanation for why he disagrees with those studies. There is no such explanation in this case. Therefore, Dr. Margolis's opinion that more than 50 percent of women implanted with mesh experience pain is **EXCLUDED** as unreliable. This aspect of BSC's motion is **GRANTED**.

Third, BSC challenges Dr. Margolis's general opinions that complications in women with polypropylene mesh products are high. Dr. Margolis explains that, when forming his opinion about the complication rates of a medical procedure, he gives the benefit of the doubt to the patient. In other words, he assumes the worst-case scenario and errs on the side of opining as to a higher complication rate to better protect a patient. This is not a reliable, scientific basis for determining the complication rates associated with a mesh device. The plaintiffs have failed to demonstrate that Dr. Margolis has sufficient scientific support to opine as to these generalized statements. Therefore, this testimony is **EXCLUDED**, and this part of BSC's motion is **GRANTED**.

2. Lack of Scientific Basis

BSC also argues that Dr. Margolis failed to provide any scientific basis for his other opinions. The plaintiffs do not address the majority of BSC's arguments on this point, and I decline to raise counterarguments for the plaintiffs when they have failed to address BSC's arguments in their briefing. The plaintiffs have not "come forward with evidence from which the court can determine that the proffered testimony is

properly admissible." *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Therefore, the following opinions from Dr. Margolis are **EXCLUDED**: (1) that the Burch procedure is more effective than polypropylene mesh slings; (2) that Xenform slings are more effective than polypropylene slings; (3) that the infection rate of polypropylene mesh is up to 100 percent; (4) that the complication rate of urethral obstruction is greater than 10 percent with polypropylene mid-urethral slings; and (5) that he has removed 10 to 15 percent of BSC products. These portions of BSC's motion are **GRANTED**.

Unlike the above opinions, the plaintiffs appear to respond to BSC's argument concerning Dr. Margolis's opinion about a lack of scientific support for the use of mesh. The plaintiffs contend that Dr. Margolis merely opines that there is a lack of *long-term* data. Contradictions in testimony should be addressed on cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). Therefore, I do not exclude Dr. Margolis's opinion on a lack of *long-term* data on reliability grounds.[2] Therefore, BSC's motion regarding this opinion is **DENIED**.

3. Expertise

[2] The plaintiffs in prior cases have responded to this same challenge in a different way. *See Sanchez*, 2014 WL 4851989, at *14; *Tyree*, 54 F. Supp. 3d at 519–27; *Eghnayem*, 57 F. Supp. 3d at 676–80. Instead of focusing on long-term data, those plaintiffs informed the court that Dr. Margolis never opined that there was *no* data supporting the benefits of polypropylene mesh, but just that there was no *credible* data on this subject. In those cases, I excluded Dr. Margolis's opinion because "it [was] still unclear why Dr. Margolis believe[d] th[o]se studies lack[ed] credibility." *Sanchez*, 2014 WL 4851989, at *14.

BSC argues that Dr. Margolis offers opinions outside the scope of his qualifications on (1) biomaterials; (2) polypropylene degradation; (3) foreign body reaction; (4) adequate pore size; (5) adequate weight of polypropylene; (6) biocompatibility of polypropylene; (7) medical device design and development; and/or (8) marketing. The plaintiffs fail to provide any argument addressing how Dr. Margolis is an expert on any of the above subject matters, beyond the basic assertion that Dr. Margolis is an established urogynecologist with years of experience with pelvic mesh products. I will not make arguments for the plaintiffs. Therefore, this aspect of BSC's motion is **GRANTED**.

4. Undisclosed Opinions

Finally, BSC argues that Dr. Margolis seeks to offer opinions that were not disclosed in his expert report and that Dr. Margolis seeks to discuss materials that were not cited to in his expert report. Testimony on direct examination using such undisclosed sources as support for his opinions is **EXCLUDED** on Rule 26 grounds. However, the court notes that two articles that BSC alleges were not disclosed—*Vaginal Mesh Contraction: Definition, Clinical Presentation and Management* and *Surgical Management of Pelvic Organ Prolapse in Women*—were included in Dr. Margolis's relied-upon list. Dr. Margolis's testimony on these two articles is not excluded under *Daubert*. Therefore, I find that this aspect of BSC's motion is **GRANTED in part** and **DENIED in part**.

For the reasons stated above, I **GRANT in part** and **DENY in part** BSC's Motion to Exclude the Testimony of Michael Thomas Margolis, M.D.

B. Thomas H. Barker, Ph.D.

The plaintiffs offer Dr. Barker as a biomaterials expert. He seeks to testify as to general opinions, such as those related to the biocompatibility of polypropylene mesh, mesh degradation, scar formation, mesh design, and mesh testing.

1. Reliability

a. *Mechanical Mismatch*

Dr. Barker opines that there is a mechanical mismatch between vaginal tissue and BSC mesh. I find this opinion to be unreliable. In comparing the elastic moduli of vaginal tissue to that of mesh in order to support his opinion as to a mismatch, Dr. Barker relied on a study finding six to seven kilopascals for vaginal tissue. However, he admits that he has no scientific basis for forming a kilopascal number for BSC mesh. Such an opinion rests on an unreliable basis. To the extent that Dr. Barker merely opines that vaginal tissue and polypropylene mesh are not composed of the same material, such an opinion is not helpful to a jury. Dr. Barker's opinion that a mechanical mismatch exists is **EXCLUDED**.

b. *Mechanical Performance Findings*

Dr. Barker's opinions on the clinical consequences resulting from the alleged mechanical mismatch between the mesh and the human body are **EXCLUDED** as unreliable as well. His opinion on the mechanical mismatch generally is excluded, and, thus, any derivative opinions are also unreliable. Such opinions are too speculative to be deemed reliable under *Daubert*.

Moreover, with respect to mesh deformation in particular, BSC challenges Dr. Barker's opinion that BSC testing revealed approximately 35 percent to 52 percent of deformation in its mesh samples. However, when questioned about this topic at his deposition, Dr. Barker admitted that he is unsure whether this testing was done exclusively on BSC products. This deposition testimony further reveals the unreliability of Dr. Barker's methodology. BSC's motion with respect to Dr. Barker's opinions on the clinical effects of a mechanical mismatch between BSC mesh and vaginal tissue is **GRANTED**.

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. is **GRANTED**.

C. Jimmy W. Mays, Ph.D.

Dr. Mays is a Distinguished Professor of Chemistry at the University of Tennessee who offers general causation opinions on the following issues: (1) the chemical structure and properties of polypropylene; (2) degradation of polypropylene by thermo-oxidative processes and in vivo; and (3) the effect of in vivo degradation on the polypropylene implant.[3]

BSC argues that Dr. Mays's opinions should be excluded because his thermogravimetric analysis ("TGA") did not replicate the in vivo environment. Dr. Mays produced certain results while testing polypropylene at very high

[3] As an initial matter, BSC attempts to incorporate by reference its *Daubert* objections to Dr. Mays's general causation opinions offered in *Sanchez v. Boston Scientific Corp.* BSC does not inform the court what these objections are or attach the *Sanchez* motion. Further, the expert report offered in *Sanchez* was authored by both Dr. Mays and Dr. Gido and is not identical to the report offered in the present case. Accordingly, I will not address the objections made in *Sanchez* and instead rule solely on the issues currently before me.

temperatures. He then concluded that the same results will occur inside the human body at much lower temperatures, but he did not provide any explanation or support for his opinion. These derivative conclusions are not the product of reliable principles and methods. Dr. Mays failed to demonstrate a reliable connection between his TGA results and his conclusions about polypropylene degradation in the human body. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. is **GRANTED**, and Dr. Mays's general causation opinions based on his TGA are **EXCLUDED**.

D. Peggy Pence, Ph.D.

Dr. Pence works as a clinical and regulatory consultant, providing advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the FDA.

1. Qualifications

BSC maintains that Dr. Pence's work as a researcher and consultant on the development of medical products does not qualify her to opine about the safety and efficacy of mesh products, as she attempts to do in her expert report. Dr. Pence has over forty years of experience in the research and development of medical devices. Over that time, she has accumulated knowledge that is relevant to this case, such as the design of clinical trials for diseases of the female genital system, the clinical testing of novel medical devices, and the content of product labeling. Accordingly, I **FIND** that Dr. Pence is qualified to render the opinions set forth in her expert report.

2. General Objections

I begin by addressing two objections that BSC raises multiple times throughout its motion, all related to the reliability of the authoritative sources underlying Dr. Pence's opinions, which include a 2006 study by the French National Authority for Health ("HAS"), the recommendations of the National Institute for Health and Care Excellence ("NICE"), and the various guidance documents drafted by the Global Harmonization Task Force ("GHTF").[4] BSC has not cited any case suggesting that the binding effect of industry standards dictates their reliability. Indeed, the Seventh Circuit Court of Appeals has suggested the opposite:

> [T]he relevant question for admissibility purposes is not whether the . . . guidelines are controlling in the sense of an industry code, or even how persuasive they are. It is only whether consulting them is a methodologically sound practice on which to base an expert opinion in the context of this case.

Lees v. Carthage Coll., 714 F.3d 516, 525 (7th Cir. 2013). Accordingly, I give no import to the non-binding nature of the HAS, NICE, and GHTF recommendations in my *Daubert* analysis and instead focus on whether Dr. Pence's reliance on these sources constitutes a methodologically sound practice.

BSC also attempts to equate GHTF standards with FDA regulations and asserts that, like FDA regulations, admission of GHTF standards, which have

[4] The GHTF, which was conceived in 1992 and replaced by the International Medical Device Regulators Forum ("IMDRF") in 2011, represented a partnership between regulatory authorities and regulated industry and sought to achieve greater uniformity between national medical device regulatory systems. The European Union, United States, Canada, Australia, and Japan were the founding members, and these entities, as well as Brazil, China, Japan, and Russia, currently form the Management Committee of the IMDRF. Dr. Pence relies on several GHTF "Final Documents" in reaching her opinions.

"regulatory purpose, history, and focus," could confuse and mislead the jury. GHTF standards do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. Although the FDA appears to have had a limited role in the activities of the GHTF, that role was not instrumental or definitive, and the work of the GHTF can be described without reference to the FDA. Accordingly, I **FIND** BSC's argument without merit.

3. Premarket Testing

Generally, BSC contends that none of the studies Dr. Pence relies on support her opinion that BSC should have performed premarket clinical trials. My review of the exhibits, however, indicates that several guidance documents supply a basis for this opinion. Additionally, although the NICE and HAS studies are not as explicit as the GHTF documents, they both emphasize the importance of clinical trials in assessing a product's safety for surgical use. Furthermore, all of these documents carry the indicia of reliability set forth by *Daubert*: the conclusions were reached after documented and validated testing, the results were published, and the testing was conducted through a defined methodology described in each paper. Therefore, I **FIND** Dr. Pence's consultation of these sources in reaching her opinion both justified and reliable.

Next, BSC argues that Dr. Pence's report lacks a discussion of the GHTF standard itself and how Dr. Pence's application of that standard led her to form the opinions contained in her report. These remaining arguments go to the weight of Dr.

Pence's testimony, not its reliability, and are therefore better suited for cross-examination. In conclusion, I **DENY** BSC's motion to exclude Dr. Pence's opinion on premarket clinical testing.

4. **Product Labels**

BSC asserts that to the extent Dr. Pence's opinions on product labeling relate to BSC's deviation from the branding requirements of the Food, Drug, and Cosmetic Act ("FDCA"), they should be excluded. I agree. As I have held several times in the course of these MDLs, expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the state tort claims than enlightenment. I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (agreeing that "alleged shortcomings in FDA procedures are not probative to a state law products liability claim"). These opinions are **EXCLUDED**.

This finding, however, does not result in the exclusion of Dr. Pence's opinion on product labeling altogether because, unlike in previous cases, Dr. Pence has a second source of information that is unrelated to the FDA (i.e., the GHTF's *Label and Instructions for Use for Medical Devices*) which I must also consider in my analysis. The GHTF document on product labels does not state—expressly or otherwise—that manufacturers should include the severity, frequency, and permanency of adverse events in a warning, nor does it state that a label should qualify the difficulty of removing the device. Furthermore, Dr. Pence does not explain how this document could be interpreted as such. Seeing no non-FDA grounds for Dr. Pence's opinion that BSC should have included this particular information in its labels, I **FIND** it

unreliable, and it is therefore **EXCLUDED**.[5]

With respect to Dr. Pence's remaining opinions on product labeling, BSC moves for exclusion because Dr. Pence never spoke to any physicians about this issue. An expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert* so long as the expert has other "sufficient facts or data" to support her opinion. Fed. R. Evid. 702. Here, Dr. Pence considered the GHTF's *Label and Instructions for Use for Medical Devices*, the DFU, several BSC internal documents, and other medical and scientific literature. I find this collection of sources sufficient for the purposes of *Daubert*. BSC has ample grounds to cross-examine and impeach Dr. Pence at trial regarding any perceived oversights in her analysis.

5. Post-Market Vigilance

In arriving at her post-market vigilance opinions, Dr. Pence exclusively considered data from the FDA's MAUDE database.[6] As I have previously explained, BSC's communication, or alleged lack thereof, with the FDA through the MAUDE database has "no bearing on whether BSC provided adequate warnings or whether its products were defective." *Sanchez*, 2014 WL 4851989, at *36. Any opinion based on data collected in the MAUDE database, which acts as an arm of the FDA, is not helpful to the jury and is therefore inadmissible. *See* Fed. R. Evid. 702 (stating that

[5] BSC raises this objection only to Dr. Pence's opinions that the label should have included information on the difficulty of mesh removal and the permanency, severity, and frequency of adverse events. My holding is therefore limited to these specific opinions as well.

[6] "The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers." FDA, *MAUDE—Manufacturer and User Facility Device Experience*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Search.cfm (last visited April 3, 2016).

the expert's specialized knowledge must "help the trier of fact to understand the evidence or to determine a fact in issue"). Because Dr. Pence's opinion on post-market vigilance appears to be entirely based on data—or lack thereof—found in the MAUDE database, I find it unreliable. Without a reliable basis, Dr. Pence's opinion on BSC's inadequate post-market vigilance is **EXCLUDED**, and BSC's motion on this matter is **GRANTED**.

6. Final Caveat: Relevance

BSC argues that several of the standards Dr. Pence relies on were not published until after the device at issue was marketed, making those standards irrelevant to this case. I **RESERVE** ruling on this matter until trial.

In sum, BSC's Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. is **GRANTED in part, DENIED in part**, and **RESERVED in part**. BSC's objection to Dr. Pence's opinions on the alleged carcinogenicity of polypropylene, uncontested by the plaintiffs, is **GRANTED**.

E. Russell Dunn, Ph.D.

Dr. Dunn is a registered professional engineer and the president and founder of Polymer Chemical Technologies LLC, a company that focuses on process and product design issues, process and product safety, and polymer product analysis.

BSC argues that Dr. Dunn is not qualified to offer opinions concerning the design, risk management, or manufacture of polypropylene mesh devices. Dr. Dunn's company, Polymer Chemical Technologies LLC, has been involved in over 200 projects focusing on polymer product design; however, none of these projects has

involved a medical device. Dr. Dunn also teaches five different chemical engineering courses at Vanderbilt University; however, he has never taught a course specific to medical devices or polypropylene. Similarly, Dr. Dunn states that he has a tremendous amount of experience assessing risk through Failure Mode and Effects Analysis ("FMEA"), but then admits that he has never been involved in developing an FMEA for a medical device. Finally, Dr. Dunn has authored many publications throughout his career; however, not one of these publications examines medical devices or how polypropylene behaves as part of a medical device.

All of Dr. Dunn's opinions are premised on his belief that the polypropylene mesh in BSC's devices will undergo oxidative degradation in the body, yet Dr. Dunn admits that he is not an expert in biomaterials or biocompatibility and that he is not qualified to opine on the way polypropylene may affect the body physiologically. I find that Dr. Dunn does not have the requisite skill, knowledge, training, education, or experience to qualify as an expert in this case, and his opinions are **EXCLUDED**. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. is **GRANTED**.

F. Scott Guelcher, Ph.D.

Dr. Guelcher is a chemical engineer offered by the plaintiffs to opine on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant. Dr. Guelcher's opinions—to the extent they are based on Dr. Dunn's testing—are **EXCLUDED** because Dr. Dunn's testing is unreliable. Dr. Dunn's *in vitro* testing failed to follow the written protocol he relied

upon in developing his test—the very protocol that Dr. Guelcher developed. Specifically, Dr. Dunn could not account for why he changed the testing solution once a week when the protocol called for changing the solution once every three days. Further, Dr. Dunn stated in his deposition that he would only use his testing to show the general behavior of polypropylene mesh in an *in vitro* oxidizing medium—not to extend what that means inside the body. Dr. Dunn's testing lacks sufficient indicia of reliability. Therefore, BSC's Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. is **GRANTED**.

G. Richard Trepeta, M.D.

Richard Trepeta, M.D., is, among other things, a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease.

1. Qualifications

First, BSC objects to Dr. Trepeta's opinion testimony on the properties of polypropylene mesh. Given Dr. Trepeta's knowledge and experience as an anatomical and clinical pathologist, I find him qualified to testify about mesh degradation, mesh shrinkage, and mesh migration, and I therefore **DENY** BSC's motion in this respect.

Second, BSC objects to Dr. Trepeta's testimony on the human clinical response to mesh implants. Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through clinical and pathologic correlation. Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which

require him to examine clinical information (through specimens, reports, or physician findings) and reach a pathologic diagnosis about a patient. Dr. Trepeta's understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response. Therefore, I **DENY** BSC's motion as to Dr. Trepeta's qualifications on this point.

2. Reliability and Relevance

BSC raises two objections to the reliability and relevance of Dr. Trepeta's opinion testimony.

a. *Reliability*

BSC contends that Dr. Trepeta's method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his expert opinion: (1) he has studied over fifty mesh explant samples in his private practice; (2) he has studied the medical literature on mesh implantation and determined that his pathological findings corresponded with the published research on mesh erosion and exposure in the vaginal wall; and (3) he has reviewed twenty-four pathology reports that he received from the plaintiffs' counsel and ascertained that the pathology reports of excised Boston Scientific products are consistent with the acute, sub-acute, and chronic categories of the disease process.

Dr. Trepeta's review of the pathology reports has a fatal deficiency—it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. The plaintiffs do not explain how or why they chose these twenty-four reports for Dr. Trepeta's review, and without such an explanation, I have no way of

assessing the potential rate of error or the presence of bias. Accordingly, Dr. Trepeta's opinions derived solely from his review of the twenty-four pathology reports are **EXCLUDED**. BSC is free to cross-examine Dr. Trepeta at trial to ensure the basis of his opinions is consistent with the court's ruling.

b. *Litigation Driven*

BSC argues Dr. Trepeta's opinions are unreliable because they are litigation driven. I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. BSC's Motion is **DENIED** on this point.

In conclusion, Dr. Trepeta's general causation opinions are admitted except for his opinions based on the pathologic reports selected by the plaintiffs' counsel for his review, which are excluded. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Dr. Trepeta is **GRANTED in part** and **DENIED in part**.

H. Vladimir Iakovlev, M.D.

Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada.

1. General Causation

BSC contends that this court should exclude Dr. Iakovlev's opinions on specimens other than Ms. Holcomb's. Dr. Iakovlev's general causation opinions are based largely on his examination of the mesh explant samples in his personal data pool. However, Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. Dr. Iakovlev testified that plaintiffs' counsel provided approximately 70 percent of the transvaginal mesh explants, but he does not know how those explants were chosen or what methodology counsel employed.

Accordingly, BSC's motion on this matter is **GRANTED**, and Dr. Iakovlev's general causation opinions based on his data pool are **EXCLUDED**.

2. Specific Causation

It is unclear whether Dr. Iakovlev intends to offer a specific causation opinion in this case because the court has not been provided with an expert report from Dr. Iakovlev specific to Ms. Holcomb. In this case, there is no evidence that Dr. Iakovlev examined the plaintiff's explanted mesh, performed a physical examination, or otherwise conducted a differential diagnosis. Assuming Dr. Iakovlev seeks to offer specific causation opinions, such opinions are not sufficiently reliable under *Daubert* and are thus **EXCLUDED**.

In conclusion, BSC's Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. is **GRANTED**.

I. Niall Galloway, M.D.

Dr. Niall Galloway is an Associate Professor of Surgery (Urology) at the Emory University School of Medicine in Atlanta, Georgia, whose practice consists largely of handling complications stemming from synthetic mesh placement in the vagina for POP and SUI.

1. Biomaterials

BSC argues Dr. Galloway is unqualified because he stated he is not an expert in biomaterials at his deposition. This testimony, however, is not dispositive. Dr. Galloway is an accomplished urologist with years of experience treating pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. Dr. Galloway's clinical experience and review of the scientific

literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction. Accordingly, BSC's motion with regard to Dr. Galloway's qualifications is **DENIED**.

BSC also contends that Dr. Galloway's opinions are unreliable because, at his deposition, Dr. Galloway could not recall whether he reviewed BSC's biocompatibility testing. This does not sufficiently undermine the reliability of his opinions and is an issue better suited for cross-examination. Accordingly, BSC's motion with regard to the reliability of Dr. Galloway's biomaterials opinions is **DENIED**.

2. Material Safety Data Sheet ("MSDS")

Next, BSC argues that Dr. Galloway is not qualified to opine on the Medical Application Caution contained in the MSDS for the polypropylene resin used to manufacture the Uphold. Specifically, BSC seeks to exclude two of Dr. Galloway's opinions on this topic:

> (1) I have seen no evidence that Boston Scientific disclosed this information to doctors and patients, nor did Boston Scientific seek further information, or do appropriate testing to determine the validity of these warnings. This is information that doctors and patients are entitled to know and need to know in order to make informed decisions regarding treatment options. Without complete and accurate information, informed consent is not possible.
>
> (2) In my opinion, placing a material that degrades, releases potentially toxic chemicals, creates a chronic inflammatory response, and was advised against by the manufacturers of the raw component represents a serious flaw in the design of Boston Scientific's transvaginal mesh devices.

Galloway Report 9–10. With regard to Dr. Galloway's first opinion, his discussion of BSC's corporate conduct will not be helpful to the jury and is thus **EXCLUDED**.

However, Dr. Galloway is qualified, as a physician, to opine that information regarding the Medical Application Caution is critical to the informed consent process. With regard to the second opinion, Dr. Galloway is not using his "scientific, technical, or other specialized knowledge" to make the factual statement that the manufacturers of polypropylene advised against permanent use, as BSC purports. Fed. R. Evid. 702. Instead, Dr. Galloway is using the information provided in the Medical Application Caution to support his opinions on the Uphold's design, which, as discussed more fully *supra*, he is qualified to provide. Accordingly, the remainder of BSC's motion with regard to the MSDS is **DENIED**.

3. Design and Adequacy of Warnings

Next, BSC contends that Dr. Galloway is not qualified to opine on the design or adequacy of warnings of polypropylene transvaginal mesh devices. With regard to design, BSC highlights Dr. Galloway's lack of experience implanting the Uphold or any other polypropylene transvaginal mesh devices. However, Dr. Galloway's experience *removing* polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him in this case. Accordingly, BSC's motion with regard to Dr. Galloway's opinions on product design is **DENIED**.

With regard to warnings, BSC seeks to exclude Dr. Galloway's opinion that alphabetizing the risks in the DFU trivializes certain adverse events. Although Dr. Galloway states that listing complications in order of importance is "convention," he fails to provide any basis for this statement, and the court has no way of assessing its

reliability. Accordingly, BSC's motion with regard to warnings is **GRANTED**, and this opinion is **EXCLUDED**.

4. Risk-Benefit Analysis

Next, BSC contends that Dr. Galloway provides no factual basis for his opinion that the risks of polypropylene always outweigh the benefits. Drawing on clinical experience and review of relevant literature—which Dr. Galloway has done—is a sufficiently reliable method of forming an opinion that the risks of polypropylene outweigh the benefits. Dr. Galloway's acknowledgement of the mere possibility of a situation where a particular patient might benefit from transvaginal mesh surgery does not undermine his overall opinion, that "for the great majority of patients, the long-term risks do outweigh the benefits." Galloway Dep. 174:11–13, Dec. 17, 2014. Accordingly, BSC's motion with regard to Dr. Galloway's risk-benefit analysis is **DENIED**.

5. Polypropylene Degradation

Next, BSC challenges Dr. Galloway's degradation opinions objecting to the conclusions that Dr. Galloway makes based on the *Clave* study. Here, Dr. Galloway considered and analyzed multiple scientific articles—not just the *Clave* study—and drew on his clinical experience to reach his opinion that polypropylene degrades. This is a reliable, scientific methodology. Any inconsistencies or discrepancies in his testimony go to its weight, not its admissibility, and BSC is free to capitalize on these matters during cross-examination. Accordingly, BSC's motion with regard to polypropylene degradation is **DENIED**.

6. Trocars

Next, BSC contends that Dr. Galloway's opinions on trocars, the instrument used to implant certain transvaginal mesh devices, should be excluded because the implantation of the Uphold does not require the use of a trocar. In response, the plaintiffs concede that Dr. Galloway's opinions related to the use of trocars will only be offered if the case involves the use of a trocar. Accordingly, BSC's motion with regard to trocars is **GRANTED**.

7. Relevant Literature

Lastly, BSC argues that Dr. Galloway's opinions are not tied to the facts of this case because he only reviewed one scientific article that specifically references the Uphold. If there are certain device-specific publications that Dr. Galloway failed to review in preparing his expert report, BSC is free to inquire about those publications on cross-examination. Accordingly, BSC's motion with regard to literature is **DENIED**.

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Niall Galloway, M.D. is **GRANTED in part** and **DENIED in part**.

J. Bobby L. Shull, M.D.

Dr. Bobby Shull is a urogynecologist offered by the plaintiffs to provide expert opinion testimony on the design and labeling of the Uphold.

1. Product Design

First, BSC argues that Dr. Shull's opinions on the design of the Uphold are unreliable because Dr. Shull did not consider BSC's design protocols. The court

agrees. Although Dr. Shull considered literature and relied on his own clinical experience, a necessary piece of data is missing to show Dr. Shull reliably applied his methodology to the facts of this case. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were departures from the norm, not followed by BSC, or lacking in any way. Therefore, any opinions concerning BSC design protocols—including the opinions listed as (2), (11), and (12) in Dr. Shull's expert report—are **EXCLUDED**.[7]

2. Product Testing

BSC also challenges Dr. Shull's qualifications to opine on the testing performed on the Uphold. Experience as a surgeon alone does not translate into experience with or knowledge about the appropriate testing a medical device manufacturer should undertake when preparing a product for the market. *See, e.g.*, *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *17 (S.D. W. Va. July 8, 2014). Accordingly, because Dr. Shull has no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices, his opinion falls short of Rule 702's requirements and cannot be admitted. Any opinion concerning BSC's product testing, or lack thereof, is **EXCLUDED**.

3. Opinions on Product Labels

Next, BSC asserts that Dr. Shull is not qualified to opine on the adequacy of the Uphold's DFU, and even if he were qualified, his opinion on this issue lacks a

[7] Because I find these opinions unreliable, I do not consider Dr. Shull's qualifications in the area of product design.

reliable basis. A urogynecologist like Dr. Shull is qualified to opine on the risks he perceives a product poses to patients and whether the product's DFU conveyed those perceived risks to physicians. I also find that Dr. Shull's forty years of experience, along with his evaluation of medical literature, forms a reliable basis for this testimony. *Kumho Tire Co.*, 526 U.S at 156 (stating that "an expert might draw a conclusion from a set of observations based on extensive and specialized experience").

BSC's remaining arguments pertaining to Dr. Shull's labeling opinions go to credibility, not admissibility, and are better suited for cross-examination. Therefore, to the extent that Dr. Shull's opinions on product labeling relate to whether the Uphold DFU conveyed the risks Dr. Shull is aware of, they are not excluded at this time. BSC's motion on this issue is **DENIED**.

4. Opinion About the MSDS for Polypropylene Resin

Finally, BSC challenges the reliability of Dr. Shull's opinion relating to whether BSC investigated the MSDS. Here, Dr. Shull attempts to opine that, because he did not find any evidence suggesting BSC inquired into the MSDS, none exists. Such a speculative leap is improper for expert testimony. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). Therefore, this opinion is **EXCLUDED**.

BSC's Motion to Limit the Opinions and Testimony of Bobby L. Shull, M.D. is accordingly **GRANTED in part** and **DENIED in part**.

K. Konstantin Walmsley, M.D.

Dr. Walmsley is a board-certified urologist with experience treating patients with stress urinary incontinence and pelvic organ prolapse. BSC challenges the reliability of Dr. Walmsley's specific causation opinions because he did not definitively rule out a native tissue procedure as a cause of Ms. Holcomb's pain. However, a medical expert need not rule out every possible alternative cause of a plaintiff's condition. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001). Here, Dr. Walmsley conducted a differential diagnosis in which he considered other causes of the plaintiff's complications. Dr. Walmsley specifically considered the plaintiff's prior native tissue procedure and articulated specific reasons for concluding that the mesh was more likely the cause of the plaintiff's pain. Such a methodology is sufficiently reliable under Daubert, so BSC's motion is **DENIED**.

V. The Plaintiffs' *Daubert* Motions

In this case, the plaintiffs seek to limit or exclude the expert opinions of Drs. Gary L. Winn, Christine Brauer, Stephen Spiegelberg, Stephen F. Badylak, Roger Goldberg, and Patrick Culligan.

A. Gary L. Winn, Ph.D.

Dr. Winn is a professor in Industrial and Management Systems Engineering in the Safety Management program at West Virginia University. Dr. Winn offers expert opinions with regard to the nature and purpose of an MSDS generally, and specifically as to the MSDS for the polypropylene used by BSC in the manufacture of its pelvic mesh products. The plaintiffs argue that Dr. Winn's opinions should be

excluded entirely, consistent with this court's decisions in *Tyree* and *Eghnayem* because his expert report is identical to the reports filed and excluded in those two cases.[8] BSC has not presented any new arguments to convince me that Dr. Winn is warranted as an independent expert. However, I acknowledge the potential need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Winn's expert opinions for trial.

B. Christine Brauer, Ph.D.

Dr. Brauer is the President of Brauer Device Consultants LLC, where she provides consulting services to the medical device industry regarding FDA regulatory requirements. The plaintiffs seek to exclude both of Dr. Brauer's expert reports filed on November 21, 2014. The first report ("FDA report") focuses on the FDA regulatory framework for surgical devices, and the second report ("supplemental report") focuses on industry standards that a manufacturer of a medical device must meet. I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or

[8] In *Tyree*, I ruled as follows:

> In his expert report, Dr. Winn describes (1) the development of the hazard communication standard; (2) the standardization of the content of MSDSs; and (3) uses of MSDSs in the field. Dr. Winn concludes that raw polypropylene is not hazardous based on anecdotal evidence involving other MSDSs; and therefore, the 2004 Chevron Phillips MSDS is extraneous. Although I believe that the warning provided in the MSDS is relevant, I do not believe an expert is required to discuss MSDSs generally or the issue of whether polypropylene requires an MSDS because of its hazardous nature. A narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning (Medical Application Caution) allegedly not heeded by BSC, not that an MSDS itself existed. This warning from the supplier could have taken any form. Accordingly, I **FIND** that Dr. Winn's opinions regarding MSDSs should be excluded in their entirety.

2014 WL 5320566, at *63; *accord Eghnayem*, 2014 WL 5461991, at *61 (quoting *Tyree*).

efficacy. Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. Accordingly, the plaintiffs' motion with regard to Dr. Brauer's FDA report is **GRANTED**, and her opinions set forth in that report are **EXCLUDED**.

With regard to the supplemental report, the plaintiffs contend that it is nothing more than Dr. Brauer's FDA report under a different cloak. I agree. Reading the two reports side by side, it appears that Dr. Brauer "supplemented" her report by removing references to the FDA and substituting the term "industry standard" instead. This "industry standard" clearly describes the FDA 510(k) process, which Dr. Brauer admits in her deposition. There is far too much overlap between Dr. Brauer's FDA report and supplemental report to avoid a regulatory mini-trial, which I have repeatedly and consistently held would confuse and mislead the jury. Accordingly, the plaintiffs' Amended Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 49] is **GRANTED**, and Dr. Brauer's opinions are **EXCLUDED** in their entirety. The court construes the plaintiffs' Amended Motion [ECF No. 49] to supersede her earlier-filed Motion to Exclude or Limit the Testimony of Christine Brauer [ECF No. 40], which the court **DENIES** as moot.

C. Stephen Spiegelberg, Ph.D.

Dr. Spiegelberg is the president and co-founder of Cambridge Polymer Group Inc., where he directs a team of scientists who perform contract research, analytical testing, and device development for the biomedical and polymer communities.

1. Position Statements

First, the plaintiffs argue that Dr. Spiegelberg's opinions regarding position

statements should be excluded because (1) they are not contained in his expert report; (2) he is not qualified to offer such opinions; and (3) he lacks any reliable methodology. Upon review, I agree with BSC that Dr. Spiegelberg does not in fact offer the opinions the plaintiffs seek to exclude. Accordingly, the plaintiffs' motion with regard to position statements is **GRANTED**.

2. FDA

Next, the plaintiffs contend that Dr. Spiegelberg is unqualified to opine on the FDA 510(k) clearance process and that such opinions should be excluded as irrelevant. In response, BSC concedes that Dr. Spiegelberg will not offer opinions on the FDA 510(k) clearance process. Accordingly, the plaintiffs' motion with regard to the FDA is **GRANTED.**

BSC limits its concession by arguing that Dr. Spiegelberg is qualified to opine on ISO standards based on his experience in the field of medical device analysis and design. I agree. Dr. Spiegelberg's current work revolves around medical device development and consultation. He is also the Task Force Chairman for the American Society for Testing and Materials ("ASTM"), which establishes standards involving the cleanliness of biomedical devices and characterization methods for polymers. Consulting on the development of new medical products requires familiarity with the applicable industry standards. Therefore, to the extent Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so. Accordingly, the plaintiffs' motion with regard to Dr. Spiegelberg's qualifications is **DENIED**.

3. Black Specks or Spots

Next, the plaintiffs argue that Dr. Spiegelberg's opinions regarding black specks in BSC's mesh are unfounded and unreliable. In his expert report, Dr. Spiegelberg states that the "black spots" are actually reflections of light on the curves of the mesh when pictures are taken, rather than inclusions or defects in the mesh. The plaintiffs contend that Dr. Spiegelberg's findings are unreliable because he did not review the photographs supplied by the plaintiffs' expert, Dr. Dunn, nor did he take his own photographs. Whether Dr. Spiegelberg took his own photographs does not sufficiently undermine the reliability of his analysis here. Challenges to Dr. Spiegelberg's ultimate conclusion with regard to the nature of the black spots are better suited for cross-examination. Accordingly, the plaintiffs' motion with regard to black specks or spots is **DENIED**.

4. **FTIR and EDS**

Last, the plaintiffs seek to limit Dr. Spiegelberg's general causation opinions based on his Fourier Transform Infrared Spectroscopy ("FTIR") and Electron Dispersive Spectroscopy ("EDS") testing. However, the plaintiffs point out that Dr. Spiegelberg's admissions regarding the limitations of these testings may also be grounds for cross-examination and thus seek only qualification or explanation of the limitations inherent to the testing in order to avoid misleading or confusing the jury. The plaintiffs will have the opportunity to adequately highlight these limitations at trial upon cross-examination. Accordingly, the plaintiffs' motion with regard to Dr. Spiegelberg's FTIR and EDS testing is **DENIED**.

In sum, the plaintiffs' Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. is **GRANTED in part** and **DENIED in part**.

D. Stephen F. Badylak, D.V.M., Ph.D., M.D.

Dr. Badylak is the Deputy Director of the McGowan Institute for Regenerative Medicine, Director of the Center for Preclinical Studies, and a tenured professor with the Department of Surgery at the University of Pittsburgh.

1. Risk-Benefit Analysis or Safety and Efficacy

The plaintiffs contend that Dr. Badylak should be precluded from opining on the safety and efficacy of polypropylene mesh devices because he has not reviewed the applicable scientific literature and he has no clinical experience using these devices. Dr. Badylak's expert report indicates that he reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices. Furthermore, Dr. Badylak explains that he is more familiar with the body of literature reviewing the safety and efficacy of surgical mesh generally, versus literature specific to any one device. This explanation does not undermine his qualifications but instead clarifies his approach. If there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiffs are free to ask him about those publications on cross-examination.

Similarly, the plaintiffs' arguments regarding Dr. Badylak's clinical experience are also without merit. Dr. Badylak has extensive experience in the field of biomaterials, including the design of implantable surgical mesh devices. Accordingly, the plaintiffs' motion with regard to Dr. Badylak's safety and efficacy opinions is **DENIED**.

2. Degradation

The plaintiffs argue that Dr. Badylak's opinions with regard to oxidative degradation based on the scientific literature are unreliable because he contradicted himself during his deposition by acknowledging the "phenomenon" of oxidative reactions. However, the plaintiffs omit Dr. Badylak's subsequent testimony, where he states that he does not believe that oxidative reactions at the surface of polypropylene results in the degradation that causes further problems. Upon review of the deposition, I do not find Dr. Badylak's testimony sufficiently contradictory to undermine the reliability of his expert opinions. Accordingly, the plaintiffs' motion with regard to degradation is **DENIED**.

The plaintiffs' Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. is thus **DENIED**.

E. Roger Goldberg, M.D.

Dr. Goldberg is the Director of the Division of Urogynecology at NorthShore University HealthSystem and an Associate Professor of Obstetrics and Gynecology at the University of Chicago Pritzker School of Medicine. He is a member of the board of directors for AUGS and is the co-inventor of the Uphold.

1. Conflict of Interest

First, the plaintiffs argue that Dr. Goldberg is biased in favor of the Uphold because he invented it and because he testified that he has been paid approximately $1.4 million from BSC since 2005. I find such an argument unavailing under *Daubert*. Bias and witness credibility are appropriate topics for cross-examination. The plaintiffs' motion with respect to this matter is **DENIED**.

2. Personal Experience

Next, the plaintiffs argue that Dr. Goldberg's opinions on the Uphold's safety should be excluded as unreliable because they are based solely on his personal experience. I disagree. *Daubert* permits an expert to rely heavily on his experience to form opinions. Even so, Dr. Goldberg's relied-upon list plainly reveals that he also considered scientific literature in forming his opinions. I decline to impose a blanket exclusion on all of Dr. Goldberg's safety opinions on the reasoning that they are based on his personal experience. The plaintiffs' motion with respect to this matter is **DENIED**.

3. Complication Rate

The plaintiffs argue that Dr. Goldberg's opinion that the complication rate for the Uphold is less than 3 percent should be excluded because it is based on a calculation of cases at his medical center and is not supported by any scientific studies. However, it does appear to be supported by scientific studies—specifically, Dr. Goldberg's data was published by a peer-reviewed journal. *See* Manhan K. Vu et al., *Minimal Mesh Repair for Apical and Anterior Prolapse: Initial Anatomical and Subjective Outcomes*, 23 Int. Urogynecol. J. 1753, 1753–61 (2012). Accordingly, I find the plaintiffs' challenges without merit, and the motion as to complication rates is **DENIED**.

4. Physical Properties of Polypropylene

First, the plaintiffs challenge Dr. Goldberg's qualification to opine on the physical properties of mesh because he is not a materials scientist, biomedical

engineer, or a pathologist and admits as much. However, his extensive clinical experience surgically treating pelvic floor disorders with mesh, as well as his review of and contributions to the medical and scientific literature adequately qualify him to opine on polypropylene. Accordingly, BSC's motion as to Dr. Goldberg's qualifications is **DENIED**.

Next, the plaintiffs challenge the reliability of Dr. Goldberg's opinion on the physical properties of mesh—specifically that the device in question does not degrade, contract, or encapsulate. Dr. Goldberg claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon relevant medical and scientific literature.

The advisory committee notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it."

Fed. R. Evid. 702 advisory committee's note to 2000 amendment (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.")).

Yet the Fourth Circuit appears more willing to "take the expert's word for it" so long as the expert has demonstrated that he or she has experience in a field writ large. *See, e.g., Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190–91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of

accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty").

On the one hand, Dr. Goldberg has based his opinions on his extensive clinical experience and a review of the medical and scientific literature, which, in the abstract, are reasonable bases from which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations—as distinguished from experience examining mesh explants. Perhaps Dr. Goldberg did not observe evidence of mesh contraction because he was not looking. Or perhaps his method of identifying and tracking the complications at issue is not scientifically sound. Additionally, sweeping statements about support within the medical community or medical literature can be difficult to assess. Although the expert report indicates Dr. Goldberg reviewed an extensive list of literature in forming his opinions generally, the court is directed to minimal specific support for the statements at issue or detail about Dr. Goldberg's methodology.

In this specific context, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh

properties based primarily on a doctor's clinical observations, or lack thereof. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

5. Response to Plaintiffs' Experts' Claims

Lastly, the plaintiffs argue that all of Dr. Goldberg's opinions in response to the plaintiffs' experts' claims should be excluded because he is not qualified and his method was unreliable. Specifically, the plaintiffs object to Dr. Goldberg's opinions on (1) vaginal mesh implantation, (2) the MSDS, and (3) the severity of complications in the DFU.

a. *Vaginal Mesh Implantation*

The plaintiffs challenge the reliability of Dr. Goldberg's opinion stating that the plaintiffs' experts are wrong that bacteria in the vagina make transvaginal mesh surgery inadvisable—specifically that polypropylene does not become routinely infected. Dr. Goldberg claims he based this opinion on his clinical experience, during which he did not encounter mesh infection, and upon peer-reviewed literature. This opinion presents the same challenges to assessing reliability as those discussed above. For the reasons discussed at length in my analysis of Dr. Goldberg's opinions on the physical properties of polypropylene, I am without sufficient information at this time to determine the reliability of his opinions on mesh infection. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

b. *MSDS*

The plaintiffs argue that Dr. Goldberg is unqualified to opine as to the MSDS for polypropylene mesh. The opinions to which the plaintiffs refer are not expert opinions. Thus, I need not address them under *Daubert*. The plaintiffs' motion with respect to this matter is **DENIED**.

c. DFU

Dr. Goldberg does not provide the court the basis of his opinion relating to the DFU, so the court cannot conclude it was the result of a reliable methodology. *See Daubert*, 509 U.S. at 590 ("Proposed testimony must be supported by appropriate validation . . . ."). Dr. Goldberg's opinion is therefore **EXCLUDED** as unreliable.

Accordingly, as set forth above, the plaintiffs' Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

F. Patrick Culligan, M.D.

Dr. Culligan is a urogynecologist offering general causation opinions related to polypropylene products generally and BSC's Uphold device in particular.

1. Safety and Efficacy

First, the plaintiffs challenge the reliability of Dr. Culligan's opinion that the Uphold is safe and effective to treat POP because Dr. Culligan acknowledged that there are only four scientific studies addressing the Uphold. She also contends that Dr. Culligan may not reliably base his Uphold opinions on studies about other POP products without detailed knowledge of how the products compare. I find these arguments unavailing because Dr. Culligan based his opinions on scientific

literature, including a published study that he conducted on the Uphold. *See* Culligan Report Ex. B.

Similarly, the plaintiffs challenge the reliability of Dr. Culligan's opinion that the Uphold is safer and more effective than traditional non-mesh POP procedures because of the lack of studies making this comparison.[9] However, Dr. Culligan's method is not unreliable just because a direct comparison study does not exist between these treatments.

Next, the plaintiffs argue that Dr. Culligan may not reliably consider his personal experience in forming his opinions because Dr. Culligan could not testify as to exact statistics about his patients. However, such detail is not required under *Daubert* to opine as to the large-scale safety and efficacy of the relevant device.[10]

The plaintiffs also point to a comment made during Dr. Culligan's deposition to argue that he failed to account for contrary literature in forming his opinions. I am satisfied that Dr. Culligan followed a reliable methodology in reaching his opinions on the safety and efficacy of the Uphold device, notwithstanding the deposition testimony. Furthermore, I decline to address Dr. Culligan's opinion on shrinkage here. The plaintiffs bring a separate challenge to such opinions, which is addressed below. In summary, the plaintiffs' Motion as to Dr. Culligans's safety and efficacy opinions is **DENIED**.

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[9] BSC contends in its response that the plaintiffs do not challenge this opinion. I disagree.

[10] The plaintiffs also challenge an opinion that Dr. Culligan asserts at his deposition—that the complication rate in his patients implanted with the Uphold is one percent. However, this opinion is not within Dr. Culligan's report. Thus, I must presume that Dr. Culligan does not plan to offer it at trial, and I need not assess the reliability of it.

2. Physical Properties of Polypropylene Mesh

Next, the plaintiffs challenge the reliability of Dr. Culligan's opinion on the physical properties of mesh, including the nonoccurrence of shrinkage, foreign body response, and degradation. Dr. Culligan claims he based this opinion on his clinical experience, during which he did not observe evidence of such mesh properties, and upon peer-reviewed literature. On the one hand, these are reasonable bases from which to form an expert opinion. On the other hand, the court does not have enough information to judge the reliability or relevance of these particular clinical observations or the methodology. Further, I have no basis to assess claims that Dr. Culligan's observations are supported by the scientific community.

For the reasons discussed at length in my analysis of Dr. Goldberg, I am without sufficient information at this time to determine the reliability of Dr. Culligan's opinions on the physical properties of mesh. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

3. Mesh Design

Next, the plaintiffs contend that Dr. Culligan is not qualified to opine as to the mesh design process. I agree. Dr. Culligan testified at his deposition that he has not designed any POP products, and the court is unpersuaded by BSC's argument that Dr. Culligan has sufficient experience with pelvic floor repair kits to opine as to the Uphold design. Dr. Culligan's opinions on this matter are **EXCLUDED**.

4. DFU

The plaintiffs also argue that Dr. Culligan is unqualified to opine as to the

Uphold DFU. Based on a demonstrated lack of knowledge as to DFUs and an admitted lack of expertise in the area, the court finds insufficient indicia of Dr. Culligan's qualification to opine on DFUs. His opinions on the DFU are **EXCLUDED**.

5. MSDS

I decline to entertain the plaintiffs' challenge to Dr. Culligan's opinions concerning the MSDS because the parties agreed as to the parameters of his testimony on this matter at Dr. Culligan's deposition. The parties agreed that Dr. Culligan could testify that "[he] didn't know what an MSDS sheet was and that he'd never consulted one." Culligan Dep. 171:19–23, Jan. 12, 2015. Thus, the plaintiffs' motion with respect to Dr. Culligan's MSDS opinions is **GRANTED**.

6. Patient Brochure

Although the plaintiffs argue that Dr. Culligan's opinions on any patient brochures should be excluded, BSC concedes he will not offer such opinions at trial. Thus, the motion with respect to this matter is **GRANTED.**

7. Opinions on FDA

Although the plaintiffs argue that Dr. Culligan's opinions concerning the FDA should be excluded, BSC concedes he will not offer such opinions at trial. Thus, the motion with respect to these opinions is **GRANTED**.

In sum, the plaintiffs' Motion to Exclude Certain Opinions and Testimony of Dr. Culligan [ECF No. 41] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**. The plaintiffs filed two separate motions addressing Dr. Culligan. The court agrees with BSC that the later Motion [ECF No. 41] reasserts and supplements

previously-made arguments and thereby supersedes the earlier-filed Motion to Exclude the Opinions and Testimony of Dr. Patrick Culligan [ECF No. 30]. Accordingly, the earlier-filed Motion [ECF No. 30] is **DENIED as moot**.

VI. Effect of *Daubert* Ruling

I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their potential admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility at trial. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VII. Conclusion

For the reasons discussed above, my rulings on BSC's motions are as follows: Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [ECF No. 32] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Thomas Barker, Ph.D. [ECF No. 35] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Jimmy Mays, Ph.D. [ECF No. 42] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [ECF No. 46] is **GRANTED in part, DENIED in part**, and **RESERVED in part**; Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [ECF No. 45] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [ECF No. 47] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [ECF No. 48] is **GRANTED in part** and **DENIED in part**; Motion to Strike and

Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [ECF No. 53] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Niall Galloway, M.D. [ECF No. 34] is **GRANTED in part** and **DENIED in part**; Motion to Limit the Opinions and Testimony of Bobby L. Shull, M.D. [ECF No. 43] is **GRANTED in part** and **DENIED in part**; and Motion to Exclude the Opinions and Testimony of Konstantin Walmsley, M.D. [ECF No. 44] is **DENIED**.

My rulings on the plaintiffs' motions are as follows: Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [ECF No. 36] is **RESERVED**; Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D. [ECF No. 40] is **DENIED as moot**; Amended Motion to Exclude or Limit the Testimony of Christine Brauer [ECF No. 49] is **GRANTED**; Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [ECF No. 51] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 52] is **DENIED**; Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. [ECF No. 37] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**; Motion to Exclude the Opinions and Testimony of Dr. Patrick Culligan [ECF No. 30] is **DENIED as moot**; and Motion to Exclude Certain Opinions and Testimony of Dr. Patrick Culligan [ECF No. 41] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part.**

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: June 7, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE